BioGenerix AG

Claims

1. A stable pharmaceutical formulation of erythropoietin containing tris-(hydroxymethyl)-aminomethane as stabilizer, whereby the formulation does not contain amino acids or human serumalbumin.

2. A stable pharmaceutical formulation of claim 1 comprising:

a) as a pH buffering agent a sodium phosphate buffer,

b) as stabilizer tris-(hydroxymethyl)-aminomethane in an amount of 10 to 200 mM and/or NaCl in an amount of 20-150 mM,

c) a pharmaceutical quantity of erythropoietin,

3. The formulation of claim 1 or 2 which is an aqueous formulation.

4. The formulation of any of the preceding claims wherein the pH buffering agent has the formula $Na_xH_yPO_4$ wherein x is 1 or 2 and y is 1 or 2 and the sum of x and y is 3 whereby the pH buffering agent is present in the pharmaceutical formulation in a range of 5 mM to 50 mM.

5. The formulation of any of the preceding claims wherein the pH ranges from 5.9 to 6.8, preferably from 6.2 to 6.6.

6. The formulation of any of the preceding claims wherein the tris-(hydroxymethyl)-aminomethane is present in an amount of 20 to 100 mM.

7. The formulation of any of the preceding claims which contains also a non-ionic detergent in an amount ranging from 0.005 to 0.1 % w/v.

8. The formulation of claim 7 wherein the non-ionic detergent is a polysorbate, preferably Tween 20 or Tween 80.

9. The formulation according to claim 8 wherein the polysorbate is not produced from materials derived from animals and wherein the content of peroxide is lower than 1.00 µmol/g.

10. The formulation according to any of the preceding claims wherein the amount of NaCl ranges from 50 to 100 mM.

11. The formulation according to any of the preceding claims which comprises further ethylenediaminetetraacetic acid in an amount of 0.1 to 0.5 mM.